Purina Mills, Inc.

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr.
Room 1-23
Rockville, MD 20857

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January 13, 1998

(Docket No. 97N-0217)
PROPOSALS TO INCREASE THE AVAILABILITY OF
APPROVED ANIMAL DRUGS FOR MINOR SPECIES AND MINOR USES

Purina Mills Inc. is a major manufacturer of animal feed, including feed for minor species, and therefore has a vital interest in the agencies effort to develop an appropriate regulatory program for the use of needed drugs for minor species uses. Most issues targeted by the agency for comment are most appropriately addressed by animal drug sponsors. **Purina Mills however has a vital interest in requirements that might be established for the inclusion of drugs in animal feeds for minor species**.

Purina is extremely supportive of the agency providing for more animal drugs for minor species, and in particular, aquaculture, gamebirds, deer farms, zoo animals, ratites, rabbits, and laboratory animals (not necessarily in that order). Purina does not believe that any one of the proposals presented in the document, will in and of itself provide needed relief, but we believe that a combination of several of the proposals could result in significant improvement in minor species drug availability.

The agencies proposal for modification of extralabel provisions of the Animal Medicinal Drug Use Clarification Act (AMDUCA) would allow extralabel use of approved drugs in minor species feed through a veterinary prescription. The agency states that this would allow medicated feeds to be considered as a dosage form product, similar to products such as injectable medications or orally administered tablets. Purina has concerns that this plan would establish a new class of prescription feeds with the same problems and concerns that the feed industry presented when the Center for Veterinary Medicine (CVM) was considering prescription antibiotics. The end result of the antibiotic prescription proposal was that CVM instead, established a class of drugs that would be subject to Veterinary Feed Directive (VFD) requirements, rather than veterinary prescription requirements.

Purina believes that the same issues and concerns articulated in response to the antibiotic veterinary prescription plan described above are equally applicable to this modification proposal. The plan however, could be made workable if a VFD were substituted for veterinary prescription requirements. The American Feed Industry Association (AFIA) has

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P.O. Box 66812
St. Louis, Missouri 63166-6812

1401 S. Hanley Road
St. Louis, Missouri 63144

presented a VFD plan to CVM. Purina supports agency consideration and adoption of AFIA's proposed VFD plan. The scope of VFD's for minor species should include all minor species, especially those named above in paragraph two.

Liability issues coupled with CVM approval requirements are presently the key deterrents to minor species drug approvals. **If CVM approves a VFD program for use of drugs for minor species, feed manufacturers should be permitted to place a disclaimer statement on such VFD containing feeds to the effect that the feed manufacturer is not responsible for the effectiveness or safety of the animal drug mixed in the feed in accordance with a VFD**. The feed manufacturer however would be responsible for assuring the proper manufacture of the feed, which would be determined through review of records required by the medicated feed GMP's (21 CFR 225) but not through assay of the feed for drug content. **Feed assays for VFD containing drugs could and would probably be problematic**.

Purina believes that this plan should be implemented by the agency as soon as possible and not have a sun set provision as suggested in the proposal. As minor species drugs become available through the approval process this plan will loose usage on its own merits. We further believe that the proposed modifications should be extended to include all animal drugs, not just therapeutic uses.

As pointed out by CVM in the proposal, animal drugs are desperately needed by minor species animal producers. Failure to have these needed tools available to animal producers has resulted in animal producers obtaining medicated feed intended for other animal species to provide needed medication for their animals. In some cases the feed may not be of the desired nutritional value, or perhaps not of the physical form suited for the minor species resulting in unneeded animal suffering and lack of drug efficacy. Unless a workable plan is adopted, this undesirable practice is likely to continue. **Purina believes that establishment of a VFD program will result in a workable solution until more CVM approvals through other modified means can be established.**

Purina would agree to meet with CVM at any time to discuss the VFD plan and specific details of implementation. We appreciate this opportunity for comment.

Sincerely,

R. E. Broyles, Director
Regulatory, Quality & Safety

cc Dave Bossman - American Feed Industry Association
Randy Gordon - National Grain and Feed Association

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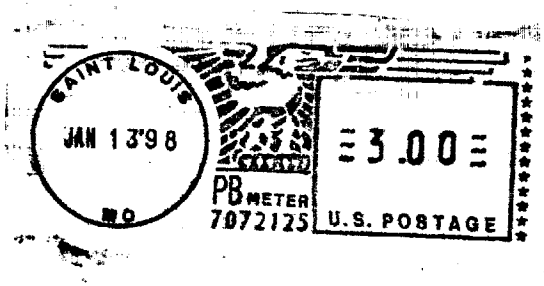

Purina Mills, Inc.
8308

1401 S. Hanley Road
St. Louis, Missouri 63

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